

# PATENT SPECIFICATION

(11) 1 297 794

DRAWINGS ATTACHED



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- (21) Application No. 61663/69 (22) Filed 18 Dec. 1969  
 (31) Convention Application No. 787 539 (32) Filed 27 Dec. 1968 in  
 (33) United States of America (US)  
 (45) Complete Specification published 29 Nov. 1972  
 (51) International Classification A61M 37/00 F04B 21/00  
 (52) Index at acceptance

A5R 33C1A 33G4 33G  
 B1D 1B1 1B4 1E 1U 2J1B2 2J1C3 2J1EU 3B  
 B1M  
 B1T 421 422 538 54X 571 573 582 602 623 626 641 646  
 662 66Y 683 684 68Y 692 693 761 764 785  
 F1A 4A

## (54) STERILE DISPOSABLE LIQUID MEDICAMENT ADMINISTRATION APPARATUS

(71) We, PALL CORPORATION, a corporation of the State of New York, United States of America, whose legal address is Glen Cove, New York, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

10 This invention relates to a sterile disposable medicament administration apparatus for administration of medicaments to a patient.

15 The administration apparatus at present in use for administering medicaments to a patient are surprisingly complex and cumbersome, and are usually arranged for manual or gravity operation. Despite the advances in modern medical science, such apparatus are very little changed from those in use a generation ago, and they are far from satisfactory.

25 A perennial problem is that of ensuring sterility of all of the components. Since the more costly components necessarily have to be reused, this involves washing and sterilizing, which in turn requires time, equipment and manpower. Because of the danger of an embolism, the apparatus has to be painstakingly cleared of air before use, and has to be air-tight.

30 A disposable apparatus that could be made up as a unit, sterilized as a unit, used and then discarded would resolve these problems. However, it has previously been impossible to design such an apparatus for marketing at a reasonable cost, because of the unavailability of the necessary components. Moreover, apparatus that could be used with a pump has been quite beyond reach, because of the need for an air eliminator, an air spring or pressure absorber, and appropriate one-way valving.

It is known that porous materials of a small pore size when wetted by a liquid are incapable of passing gases at fluid pressures below the so-called "bubble point" of the material. The bubble point is defined as the characteristic pressure at which the first bubble of air appears, when such a material is pressurized with air while immersed just under the surface of a liquid. The bubble point effect is well known from U.S.A. Patent No. 3,007,334. In fact, the method and apparatus according to that patent make it possible to determine the maximum pore size of filter elements from the pressures at the bubble point, since these pressures are directly correlated with the pore size of the filter.

It has been proposed that this phenomenon be employed to prevent the passage of air to patients by insertion in the administration line leading to the patient of a microporous filter material which is preferentially wetted by the liquid being administered. Such a device when saturated with liquid will not permit the passage of air to the patient, so long as the fluid pressure is below the bubble point of the filter. However, the problem with such devices is that although they block the passage of air, they do not vent it, with the result that the air held back by the filter can cover the surface of the filter, restricting flow, or even blocking it, if the surface is completely covered, and increasing the pressure drop across the filter, with the result that the bubble point of the filter element can be reached sooner than expected, after which the blocked air will pass through, virtually all at once. Furthermore, the presence of this type of filter in the line makes it difficult if not impossible to clear the line of air once the filter has been wetted, which means that after the line has been used, it must be thoroughly dried out so as to dry

the filter, before it can be cleared of air for the next use. This drying procedure is not always feasible, however, particularly where filters must be steamed, sterilized, or hot-water sanitized before use, and are therefore wetted completely before use.

The problem is particularly troublesome with microporous filter materials having pores of less than one micron in diameter. Such filters are intended to filter out harmful microorganisms from fluids, but in such filters the pressure differential needed to force air through a filter wetted with a liquid can be as high as 30 psi, as a result of which complete filter blockage can result from the presence of air in sufficient quantity in the system to cover the surface of the filter.

It is possible to avoid these difficulties to a certain extent by the use of filter materials that contain both hydrophobic and hydrophilic portions. The hydrophilic portions will pass the liquid, and the hydrophobic portions will not be wetted by liquid, and will therefore remain open for passage of gas therethrough. Such filters will pass air and other gases, but of course they cannot be used in medical applications or other applications to separate air or gas from the liquid.

Another difficult component in a disposable administration apparatus is the pump. It is quite impossible to permit the medication to pass through a conventional pump, for sanitary reasons. A syringe pump presents itself as a feasible alternative. Surgical syringes are available, and can accurately meter fluid. Moreover, since they employ a piston and cylinder, they have proved suitable for accurately pumping measured small amounts of fluid for laboratory use.

One such laboratory syringe pump is shown in U.S.A. Patent No. 3,259,077 which discloses a pump assembly which employs a surgical syringe as the means for pumping measured amounts of fluid. However, the valve assembly that is associated with the apparatus is rather complicated, and the pump itself relatively expensive to manufacture. Moreover, the syringe is a part of the assembly, which is adapted to readily employ only syringes of a fixed size. It is clearly not practical to have several pumps of different sizes for each size syringe, and it is also necessary to sterilize the syringe after each use.

Another essential component, if a syringe pump is to be used, is a check valve arrangement to ensure one-way flow through the apparatus, to and from the syringe. This is a special problem in itself.

Syringes of course are widely used in medicine for the injection of fluids into the body, or for withdrawal of fluids from the body. Frequently, the volume of fluid that is to be injected or withdrawn is greater than the available capacity of the syringe. This

requires two or more injections or withdrawals, with a corresponding number of insertions of the syringe needle into the body.

In order to avoid this problem, Y-couplings have been provided, such as are described in U.S.A. Patent No. 986,263, which permit the connection of the syringe to an additional reserve container. The coupling is provided with valves, to regulate the flow of fluid in the proper direction, and prevent any backflow thereof, and these valves are connected with the Y-coupling by a section of flexible tubing. This device is large and clumsy, however, and has never been widely employed, partly because it is really only useful with syringes of very large volume, whereas the problem most frequently is encountered when the syringes have a very small volume. In such cases the Beville device is virtually useless.

In accordance with the present invention, there is provided a sterile disposable apparatus for administering gas-free liquid to a patient, comprising a connector having three branch passages one of which has a non-return valve adapted to allow the admission to the connector of a gas-containing liquid, and another of which has a non-return valve adapted to allow the exit of the gas-containing liquid from the connector and is connected by tubing to an air eliminator in an air and liquid tight manner, the air eliminator being adapted to remove gas from the gas-containing liquid; and delivery means connected by tubing with the air eliminator in an air and gas tight manner for delivery to a patient of gas-free liquid received from the eliminator.

The connector lends itself to fabrication by molding or casting to a predetermined shape. This not only simplifies the manufacture of the connector, but also makes it suitable for mass production, and thus reduces its cost.

In a preferred embodiment of this apparatus, the connector or coupling is made entirely of plastics material with the exception of the check valves, which can be of a plastics or rubber material, and the plastics material components of the coupling are all united together, with the check valves locked in position, and with mating and/or standard fittings, joints or sockets in each of the three passages, for coupling thereof to a syringe of conventional construction, the delivery means, and a fluid reservoir. A preferred type of mating joint or socket is a Luer fitting or Luer-Lok.

The connector preferably has an extremely small internal volume or fluid retention. This is usually less than 1cc., and is preferably less than 0.1 cc. This means that quite high operating pressures can be achieved using conventional medical syringes, and also that

very little of the fluid being delivered is wasted within the connector.

The connector can be made of a rigid, non-pressure-deformable material, which means that none of the available fluid pressure delivered via the syringe is lost in dis-  
5 tending the connector.

The connector also includes in a preferred embodiment a resilient foam material which normally holds the jaws of one of the check valves in a fluid delivery passage closed, but with sufficient resilience to permit their opening under a predetermined fluid pressure, and nonetheless preventing leakage through  
10 the valve at lower fluid pressures.

The air eliminator is capable of separating gases and liquids and preferably of venting the gas. In this way, blockage of the administration apparatus by the build-up of an air lock is avoided, while at the same time the entrained air is entirely eliminated from the liquid. Thus, a device in accordance with the invention is particularly adapted for medicinal applications, where  
20 air must be vented from the administration apparatus, and must also be absolutely prevented from reaching a patient receiving an injection of the fluid. In a preferred embodiment, the air eliminator also is capable of removing harmful microorganisms, so that the liquids and/or gases passing through the administration apparatus are sterilized at the same time.

The air eliminator may comprise, a housing; a chamber in the housing of which  
35 chamber one wall comprises a filter material that is wetted by a liquid to be passed through the housing, and another wall comprises a filter material that is not wetted by the liquid passing through the housing, but in fact is liquid-repellent; an inlet in the housing for delivering fluid comprising air and liquid to the chamber between the liquid-wetted and liquid-repellent filter materials;  
40 a liquid outlet in the housing on the opposite side of the liquid-wetted material to the inlet; and an air outlet in the housing on the opposite side of the liquid-repellent material to the inlet. Both the liquid-wetted and the liquid-repellent materials preferably have a pore size less than about 0.3 micron, through which size pores harmful micro-organisms cannot pass. The eliminator is preferably made of plastics material and are  
50 bonded or fused together in a one piece construction.

An air cushion or spring associated with the air eliminator is preferably normally connected to the chamber upstream of the liquid-wetted and liquid-repellent filter materials. The air cushion or spring may comprise an air-filled receptacle having as the only means of fluid access thereto a fluid connection to the upstream side of the air eliminator.

65 The several components of the sterile

medicament administration apparatus of the invention are easily assembled (after preparation as described hereinafter) and interconnected by flexible tubing. The tubing can be attached to the fluid inlets and outlets provided on the components for this purpose, preferably bonded thereto by heat-fusing, solvent-bonding, or by an adhesive. The apparatus is then sterilized in an oven or in a steam sterilizer, using the conventional sterilization techniques. It can then be sealed hermetically in a sterile package, and is ready for storage or shipment, and use whenever desired.

In the accompanying drawings:

Figure 1 represents a plan view of a sterile disposable medicament administration apparatus in accordance with the invention, assembled and ready to attach to a syringe pump drive device and supply bottle;

Figure 2 represents a plan view of the system of Figure 1, connected to a syringe pump drive device and supply bottle, and ready for use;

Figures 3 to 15 represent detailed views of the essential components of the assembly of Figure 1;

Figure 3 is a view in cross-section of a typical twin valve T-connector in accordance with the invention, employing duck-bill check valves;

Figure 4 is end view, taken along the line A—A of Figure 3, and looking in the direction of the arrows;

Figure 5 is a view of an embodiment of a syringe pump with the T-connector shown in cross-section;

Figure 6 represents an exploded view of one type of air eliminator in accordance with the invention, in which liquid-wetted and liquid-repellent filter materials are at opposite sides of the chamber;

Figure 7 is a top view of the air eliminator of Figure 6 in assembled form;

Figure 8 is a cross-sectional view of another embodiment of air eliminator in which the liquid-repellent and liquid-wetted filter materials are arranged concentrically;

Figure 9 is a perspective view of the air eliminator of Figure 8;

Figure 10 is an end view of another embodiment of the air eliminator;

Figure 11 is a longitudinal section of the air eliminator of Figure 10, taken along the lines A—A of Figure 10, and looking in the direction of the arrows; and

Figure 12 is a cross-sectional view of the air eliminator of Figure 10;

Figure 13 is a cross-sectional view of another embodiment of the air eliminator in accordance with the invention, in a disk-shape, with two gas vents at the side of the disk;

Figure 14 is a view of one side of the air eliminator of Figure 13;

Figure 15 is a view of the other side of the air eliminator of Figure 13.

The administration apparatus of Figures 1 and 2 comprises a visual flow indicator 1, made of transparent flexible plastics material such as polyvinyl chloride, in tubular form, with the ends 2, 3 pinched and permanently heat-sealed to a tube connector 4 for attachment to a supply bottle, and a flexible tubing 5 which connects with a T-connector 10. The details of the T-connector are shown in Figures 3 to 4. The tubing 5 is bonded in a leak-proof seal to the leg 11 of the T-connector, in which is disposed a check valve 12, in this case, a duck bill valve, which ensures that flow is only in one direction through the leg 11 towards the T-junction chamber 54 in the T-connector. To one of attached a syringe 20 which is inserted in a syringe pump drive device 21, as is more particularly shown in Figure 5.

The third leg 15 of the T-connector is attached to a tubing 16, which is bonded thereto in a leak-proof seal. The tubing runs to the inlet connector 31 of an air eliminator 30, from which air is vented via the port 32. The details of the air eliminator are shown in Figures 6 and 7.

Attached to an inlet connector 33 of the air eliminator is an air spring or cushion 34, in the form of a dead-end piece of flexible tubing, filled with air. As the syringe pump advances on its pressure stroke, with pumping movement of the plunger 22 of the syringe 20, a pulse of fluid pressure advances through the apparatus, and its presence is indicated by an advance of fluid in the air spring 34, compressing the air in the spring. The degree of compression is proportional to the fluid pressure, and therefore the spring 34 can also serve as a pressure gauge, from which the pressure can be read off by appropriate gradations 35 of a pressure scale marked on the spring 34. This spring has the function of taking up the pressure surge, and equalizing pressure to some degree beyond the air eliminator 30. If the flow through the needle is low, the spring can even ensure a steady fluid flow through the needle, evening out the pressure surges in fluid flow from the syringe pump.

In operation, the tube connector 4 is attached to the stopper 6 of a supply bottle 7, as shown in Figure 2, and the syringe 20 is fitted in the cradle of a syringe pump drive device 21. The needle 41 is at this point not inserted in the patient. The pump is started, whereupon fluid is pumped from the supply bottle 7 through the tubing 6, connector 4, visual flow indicator 1, tubing 5, T-connector 10, syringe 20, tubing 16, air eliminator 30, tubing 37, needle adapter 38 and needle 41, clearing air from the apparatus. The needle is then inserted in the patient, and administration begun.

As the syringe pump delivers a volume of fluid via the T-connector through tubing 16, a comparable volume of fluid enters the air spring 34, compressing the air in the air spring, while fluid flow proceeds via the air eliminator at a reduced pressure through tubing 37 to the needle. The syringe pump on its suction stroke draws liquid from the supply bottle 7, and flow in tubing 16 ceases, whereupon fluid pressure drops. The compressed air in air spring 34 now exceeds fluid pressure in the air eliminator 30 and beyond, and forces fluid in the air spring into the air eliminator 30. Since the twin valve T-connector 10 prevents reverse flow in tubing 16, liquid flow continues in tubing 37 to the needle, now under the pressure of the compressed air in the air spring. If the volume of the air spring is sufficient, this flow can continue until the syringe pump has ended its suction stroke and begun its pressure stroke, so that a steady flow of liquid at the needle is obtained.

The visual flow indicator 1 is of conventional construction, and any type of such indicator can be used. It is preferably made of transparent material, although translucent materials can also be employed, and is best made of plastics material or glass, such as polyvinyl chloride, polyethylene, polycarbonate, polypropylene, or polymethyl methacrylate.

It is composed of a small chamber larger in diameter than the tubing connecting it with the remainder of the administration apparatus, or than the tubing connecting it to the supply container, so that the flow of fluid therethrough can be readily observed.

The twin valve T-connector 10 shown in Figures 3 and 4 has a coupling housing 55 that is moulded in one piece entirely of plastics material, in this case, a modified phenylene oxide resin. However, other thermoplastics or thermosetting mouldable or castable plastics materials can be employed, such as ethyl cellulose, cellulose acetate-butyrate, cellulose propionate, nylon, polyphenylene oxide, polyethylene, polypropylene, polytetrafluoroethylene, polychlorotrifluoroethylene, polystyrene, polyvinyl chloride, polycarbonates, polyoxymethylene, epoxide resins, urea-formaldehyde, melamine-formaldehyde, phenol-formaldehyde, 2-methylpentene polymers, and polyester resins.

The coupling body constitutes a unit made in three pieces, the housing 55, and two fitting inserts 52 and 53, all of which are bonded together by softened integration of the plastics material with a solvent, at their adjoining contacting surfaces. The coupling housing 55 as shown is in a T-shape, with three legs, 11, 14, 15, each of which bears a central passage 17, 18, 19, respectively, meeting at central chamber 54 of the housing. A T-shape has been adopted for convenience, but

it will be evident that the configuration of the coupling is in no way critical. The three passage-bearing legs thereof can be set in the angles of a Y, or at any desired angle other than the 90° angle shown in Figure 3. The 90° angle is preferred, however.

The central passages 17, 18 and 19 intersect at the centre of the coupling housing. The coupling housing 55 at the outer end of the passage 17 has a reentrant portion 60 that defines a valve seat 61. Beyond the valve seat 61 is a wide bore 62 that extends to the exterior of the housing. A check valve 12 of the duckbill type is placed at the inner end of the bore 62 with the duckbill 68 facing inwardly from the valve seat 61, and with a base flange 66 abutting against the valve seat 61 in a leak-tight seal. The valve can be of any resilient or flexible heat-, water-, and solvent-resistant material, such as natural or synthetic rubber, for example, neoprene, or butadiene-styrene-acrylonitrile polymer, polypropylene, polyethylene, ethylene-propylene polymers, polyvinyl chloride or rubber hydrochloride resin. The base flange 66 of the valve is locked in position in the valve seat 61 by the fitting insert 52, which fits snugly in the bore 62 with its external wall bonded thereto by way of a solvent-formed bond.

The check valve 73 has the duckbill 68 enclosed snugly in a foam material spring 13, which is of a resilient open cell foam sheet material, with through pores, such as foam rubber, foam styrene-acrylonitrile rubber, foam polyethylene, foam polypropylene, foam silicone rubber, foam nylon, foam polyvinyl chloride or polyether-based or polyester-based polyurethane foam material. This spring tends to hold the duckbill closely snugly, and it can open only by a fluid pressure sufficient also to compress the foam material, thus providing a higher fluid opening pressure than would otherwise be the case, and aiding in preventing leakage from a supply bottle through the valve 73. The foam material is highly porous, with through pores, of the order 0.005 to 0.025 inch in diameter, and even when compressed upon separation of the lips of the duckbill, fluid flow is permitted there-through. The foam material also serves as a filter, to a certain extent.

It will be appreciated that the fitting insert 52 can also be held in the bore 62 by a press fit, and it can also be bonded therein by a suitable binder. The sides of the bore can be threaded, and the fitting insert 52 correspondingly threaded, so that it can be screwed tightly into the bore, in which event the check valve 12 can be removed for replacement. In the preferred embodiment, however, the fitting 52 is permanently fixed in the bore 62. In all cases, the fitting holds

the flange 66 of the valve 12 tightly against the valve seat 61 in a leak-tight seal.

It will be evident that the check valve 12 ensures that flow in the passage 17 is only in the direction shown by the arrow.

The fitting 52 has a central passage 67 connecting at its inner end with passage 78 through the check valve 12. In the bore of passage 67 is bonded one end of tubing 5.

At the inner end of the passage 19 in arm 15 the housing 55 is formed with a reentrant portion 70, defining at its inner end a valve seat 71, against which is seated a flange 72 of a check valve 73, also of the duckbill type. This check valve faces outwardly, so that flow in the passage 19 proceeds only in the direction shown by the arrow.

Beyond the valve seat 71, the housing 55 widens, and defines a bore 74 extending to the exterior of the housing 55. Held within the bore in a snug fit is the fitting insert 52, the inner end of which abuts against the exterior face of the flange 72 of the check valve 73 and holds it tightly in position against the valve seat 71, in a leaktight seal. The fitting insert 52 has an internal passage 77 through the check valve, and this passage receives the tubing 16, which is bonded therein.

The passage 18 does not contain a valve, and is adapted to receive in a press fit the delivery tip of the syringe 20 which pumps fluid through the T-connector. The syringe tip is shown in dashed lines in Figure 3.

The operation of the T-connector of Figure 3 is as follows. The delivery tip of a piston-type syringe 20 is pressed into passage 18 of arm 14. On the suction stroke the piston of the syringe on arm 14 draws fluid from the tubing 5 via passages 78, 17 into the interior chamber 54 of the housing 55 and thence into the syringe, and then on the pumping stroke the piston pumps this fluid through passages 18, 54, and 19 into and through the tubing 16. Thus, a volume of fluid is drawn from the supply bottle equal to the capacity of the syringe (as determined by the stroke of the piston, and area of the bore of the syringe) attached to the arm 14, and then this volume is ejected via tubing 16 with each stroke on the piston. It will be evident that a lesser volume can be drawn, if desired, and that the volume is completely controllable by the user, according to the length of the stroke of the piston.

The actual capacity of the chamber 54, within check valve 73, externally of check valve 12, and externally of the syringe tip, including the volume of passages 17, 18 and 19, can be as little as 0.1 cc., or even smaller.

Any type of check valve can be employed. The duckbill-type of valve with duckbill tips shown in Figures 3 and 4 is preferred. There can also be employed poppet-type valves,

ball-type valves, umbrella-type valves, and flat-type valves.

The foam material spring is useful to hold any of these types of valves snugly closed and thus prevent leakage at all pressures below a predetermined minimum valve crack-open pressure. The spring is of resilient foam material and is interposed between the valve 73 and the housing of the T-connector in such a position that the valve cannot open without compressing the foam material spring 13. Preferably, the foam material is under some compression when the valve is closed, so that it aids in keeping the valve in a closed position, in the manner of a spring.

When the valve 73 opens, it compresses the foam material, and at the same time fluid comes into contact with the material, and must pass through it to escape from the valve. The material thus acts against an open valve with even greater resistance than against a closed valve, and this aids in closing the valve to a tight snug seal as soon as fluid pressure is reduced to below the crack-open pressure.

The desired effect can be obtained by filling the fluid passage downstream of the valve 73 with a foam material plug, which is in close abutment to the valve on the side which moves outwardly in opening the valve. Thus, the plug can surround the jaws of a duckbill valve, or engage the downstream face of a flap or umbrella valve. If the plug is retained under compression in this position by some means in the passage, such as a constriction, or a flange, it will tend to hold the valve closed and will be further compressed when the valve opens.

Other arrangements will be apparent. For instance, a sheet of foam material can be folded in a U or V over the jaws of a duckbill valve.

While the orientation of the arms containing the valves which is shown in the Figures is the preferred one, it will be apparent that the arms may be in other orientations. The arrangement shown prevents the entrapment of air in the chamber of the coupling, and it also prevents the kinking of flexible hose or tubing connected to the arms 11, 15.

A special feature of embodiments of connectors in accordance with the invention is that it is possible to draw fluid from any closed container without the need of venting the interior of the container, so as to relieve the vacuum that results. This is because of the extremely small internal volume of the T-connector. Due to the small internal volume (less than 1 cc. and preferably less than 0.1 cc.) a high compression ratio is obtained. This makes it possible to obtain pressures in a container of less than the vapor pressure of water and many other liquids. This means that no air need be introduced

into a container to pump liquid out of the container.

In addition, it is possible to pump gases out of a container until extremely low pressures are reached. For example, with a connector having 0.1 cc. internal volume and a 50 cc. syringe, it is possible to pump a gas out of a container until a vacuum of  $1/500$  atmosphere is reached. Moreover, it is possible using a connector in accordance with this invention to pump gases with almost 100% volumetric efficiency.

The construction of the T-connector is such that it is possible to hold and cast it from any plastics material that is thermoplastic or thermosetting but in a moldable or castable stage of polymerization. It can in fact be made easily in one unit from as few as five pieces, the coupling housing, the two valves, and two fitting inserts or valve insert pieces. If desired, the coupling housing also can be made in two parts, and bonded together with the valves and socket adapters in place. The several parts can be permanently bonded together, by heat-sealing, integration of adjoining parts by fusing or solvent-bonding, or by an adhesive or bonding agent.

It may also be possible in some cases to mould the coupling housing one piece, so that the valves can be inserted in their respective passages and sealed in place, with the ends of the passages being molded in the shape needed for reception of the desired types of connections. This reduces the total number of pieces to three; and eliminates the fitting insert pieces shown in the drawings.

The resulting device is simple, and easy to handle and clean. It is so inexpensive that it can be discarded after one use, for sanitary reasons. Since it can be entirely of heat-resistant and solvent-resistant material, it can be sterilized before use, and stored in a sterilizer for a considerable period of time, if desired, without deleterious effect.

It is possible to fabricate a coupling that is capable of withstanding the pressure necessary to pump from any type of container because the coupling can be formed by a molding or casting technique from non-resilient plastics materials with walls of a thickness to resist any fluid pressures that are likely to be encountered. In this respect, a nonresilient or rigid coupling in accordance with the invention is superior to couplings which have employed as a component of the construction a flexible tubing which incorporates the valves or connections to the pumping syringe or fluid supply.

A syringe pump drive device is shown in Figure 5 and comprises a base 8 of plastics material housing a motor (not shown). The motor is operatively connected to an eccentric drive mechanism by a drive wheel 9, via a motor shaft 11. An eccentric drive pin 23 is located on the drive wheel 9. The drive

pin is operatively connected to a pivoted yoke drive mechanism 24. The yoke comprises a pivoted bar 25 having a slotted portion at one end 26, for reception of the pin 23, and a lever portion 27, at the other end thereof. The drive pin 23 is located within the slotted portion 26 for pivotally moving the lever portion 27 upon rotation of the drive wheel 9. The lever portion 27 engages a plunger drive mechanism 28 for reciprocally moving a syringe plunger 22 within the syringe 20. The plunger drive mechanism 28 comprises a carriage 40 having a slotted portion 39 which engages the end 42 of plunger 22. The carriage is movable in the same direction as is the plunger in a slot (not shown) via a key 43. A set screw 44 is located adjacent to the lever portion 27 of the yoke drive 24 to limit the extent of the reciprocal motion of the plunger 22, upon pivotal motion of the yoke drive 24.

The syringe, which consists of a body portion 45, the plunger portion 22, a flanged end 46, and an apertured tip 47, is mounted on the housing with the plunger end 42 within the slotted portion of the plunger drive mechanism and the flanged end 46 within a pair of pincer snap clips 48. The pincer snap clips are composed of a rigid section 49a and a resilient arm member 49b. The resilient arm is made of spring steel and tightly holds the flange of the syringe in position as the plunger of the syringe is reciprocated within the body portion 45. The syringe is easily demountable from the assembly by merely sliding it from the snap clips 49, and removing the plunger end 42 from the plunger drive mechanism 28.

The apertured tip of the plunger is attached to the leg 14 and passage 18 of T-connector 10.

In operation, upon rotation of the motor shaft 11, the drive wheel 9 is rotated, thus causing eccentric motion of the pin 23. This pin moves the lever 27 of the yoke drive 24, thus causing reciprocal motion of the plunger within the body of the syringe. Fluid is pumped through the T-connector from the supply bottle 7 into tubing 16 in measured amounts, according to the length of the stroke of the plunger and the bore of the syringe body.

The syringe and T-connector can be readily removed from the pump assembly by merely withdrawing the syringe from the snap clips and the yoke and plunger drive mechanism, in the manner described.

The syringe used in the medicament administration apparatus is an ordinary surgical syringe. Such syringes comprise a hollow cylinder having an apertured tip formed at one end and a laterally extending flange at the other end. The flange is normally provided as a convenient place for gripping the syringe when it is held in one

hand. A plunger is provided for reciprocable movement within the cylindrical body. The plunger has an end which extends from the flanged end of the syringe. The plunger is fitted in a substantially fluid-tight seal against the walls of the cylindrical body of the syringe and forms with the body a piston and cylinder pump. The seal on the plunger is normally maintained by a rubber seal. On the pumping or pressure stroke, the plunger pumps and so forces fluid from the syringe body through the tip, and on the suction stroke the plunger draws fluid into the body through the tip, for the next pumping or pressure stroke.

Surgical syringes are normally made from plastics material such as polyethylene or polypropylene; however, syringes made of any material that is inert to the fluid being pumped, such as glass, nylon, and polytetrafluoroethylene, are suitable for use in this invention. The material is preferably transparent or translucent, but it need not be.

The syringe can be of generally any size, length and diameter, and of any capacity. Capacities from about 1 cc. to about 10 cc. are preferred.

The syringe is supported on a base which can normally also serve to house or support the drive means for the assembly. The case can be made from any material, such as wood, plastics material or metal. Plastics materials, such as nylon and polycarbonates, are preferred. The base can be formed in any desired or convenient shape, such as a cube.

One preferred syringe mounting member is a clamp of the snap clip type. The snap clips can be provided on the base in position to grasp the flanged portion of the syringe and, additionally, if desired, the cylindrical body of the syringe also.

The snap clips which engage the flanged portion of the syringe prevent any longitudinal displacement of the syringe which might occur when the plunger is reciprocated. Moreover, by providing clips which grasp the flanged portion guide firmly, it is possible to prevent any motion of the syringe at all. This makes it possible to employ only one set of clips which engage the flanged portion of the syringe to secure the syringe in position on the base.

If desired, an additional snap clip can be provided to engage and support the cylindrical body against any lateral displacement of the syringe which might otherwise occur.

Snap clips are preferred, since they are readily available and easily fabricated for special application. Moreover, they are long-wearing and simple to use. They permit easy insertion, removal and replacement of the syringe on the assembly, and can readily accommodate a wide range of

syringes of different sizes, without any special adjustment.

A preferred snap clip for the flanged portion of the syringe comprises a pincer-shaped clip employing a rigid support member and a resilient pincer arm which bears against the support. The flange is inserted between the pincer arm and the support and is held in position therebetween by the spring force of the arm. This type of clip is preferred, since it has been found to provide firm support for the syringe on the base without any additional support members. It is adapted to readily accommodate syringes of different sizes since the size of the flanged portion of the syringe does not vary greatly for different syringes. A clip of the type described above also permits easy insertion and removal of the syringe and accompanying administration apparatus from the syringe pump drive assembly.

Snap clips are normally made at least in part of a highly resilient material, such as spring steel, or hard long-wearing resilient plastics, such as nylon or polypropylene.

Other suitable snap clips can be preferably C- or U-shaped, depending upon the portion of the syringe they are to hold. For example, a snap clip that is positioned to hold the cylindrical body should be "C" shaped and be oriented such that the body of the syringe is inserted into the open mouth of the "C".

Another snap clip which can be used to engage the flanged portion of the plunger should be normally shaped as a narrow "U" and be oriented such that the flange is inserted into the narrow open slot between the arms of the "U".

It is also possible to provide snap clips which are of adjustable tension to ensure a tight grip on any size syringe used. Other mounting members for holding the syringe in place, such as clamps of all types, can be used. It is to be noted, however, that any mounting should be adapted to hold the syringe in a manner such that insertion and removal of the syringe from the assembly is readily accomplished.

The mounting members can be fixed in position on the base, and need not be movably mounted in order to hold different capacity syringes. This is due to the fact that the bodies of syringes of different capacities normally vary most in body diameter. This, however, does not affect the positioning of the mounting members, and thus they need not be movable on the base. However, if desired, the mounting members can be made adjustable on the base to occupy corresponding positions on each different syringe.

The tip of the syringe communicates with the T-connector through which the fluid is pumped from the supply bottle to the air

eliminator and thence to the needle or other administration means.

The drive mechanism that is used in the instant pump assembly to reciprocate the plunger of the syringe is preferably an eccentric drive means that is powered by an electric motor. The motor can be housed in the base and be operatively connected to the eccentric drive member by a motor shaft. The eccentric drive member can be for example a cam, or a Scotch yoke assembly. The drive mechanism, however, need not be an eccentric drive apparatus. Any mechanism adapted to convert the rotational motion of the motor to translational movement of the plunger of the syringe is suitable.

The drive mechanism should be disposed in a position such that rotation of the motor causes the drive mechanism to bear against the plunger of the syringe and cause reciprocal movement thereof.

If a cam drive is used, a spring can be employed as part of the drive mechanism to return the plunger to its original position, after the cam has forced the plunger to move inwardly. A compression spring disposed between the flanged portion of the cylindrical body and the end of the plunger is preferred.

The length of the movement of the plunger and the internal volumetric capacity of the syringe together determine the amount of fluid pumped on any one stroke. Means, such as stops, set screws, and lost motion linkages, can be provided to precisely control the length of the plunger movement.

The air eliminator 30 of *Figures 6 and 7* comprises a rigid round transparent polymethyl methacrylate box housing 50 formed in three parts, an upper portion 51, a central annulus 56, and a lower portion 57, between which are fitted O-rings 58. These housing portions have thick wide walls, with four through bores 59, through which pass bolts 63, so that the three housing portions are held together in one piece.

Each housing portion is of a molded construction. Moulded as an integral part of the central annulus 56 are the two connectors 31, 33, and the lower portion is provided with a similar liquid outlet 36. For the same purpose, the top of the portion 51 is provided with port 32, which serves as an air gas vent, but two annular openings can also be provided. Tubing 16 is attached to inlet 31, air spring or cushion 34 to connection 33, and tubing 37 to outlet 36.

A disk 64 of liquid-repellent filter material, 0.1 micron average pore diameter, is held in the bite between a ledge 65 of the housing portion 56, and a perforated support member 69, made of polypropylene sheet, with  $\frac{1}{16}$  inch holes on 0.1 inch centres. A disk 76 of liquid-wetted filter material is

held in the bite between a ledge 65<sup>1</sup> of housing portion 56 and a perforated support member 75 of the same material as the member 69. The central housing portion 56 thus serves as a spacer ring, which fits between the portions 51 and 57 of the housing, supporting the liquid-repellent and liquid-wetted filter materials 64 and 76, and the span between ledges 65 and 65<sup>1</sup> thereof determines the width of the space or chamber 80 therebetween. This width can for instance be from 0.5 to 4.5 mm. The O-rings 58 assist in maintaining a liquid-tight seal between the filter materials and the housing portions 51, 56, 57. In like manner, the depth of a recess 81 in the housing portion 51 determines the width of the space or chamber 82 between the filter 64, and the housing portion 51, and the depth of a recess 83 in the housing portion 57 determines the width of the space or chamber 84 between the filter 76 and the housing portion 57.

The liquid-repellent filter 64 was prepared as follows:

A microporous filter material in sheet form was prepared, following the procedure of Example 1 of U.S. Patent No. 3,353,682. The average pore size was 0.1 micron and the maximum pore less than 0.35 micron as determined by 100% removal of the bacteria *Serratia marcescens*.

An aqueous fiber dispersion was prepared containing 5.4 g/l. of crocidolite type asbestos fibers having an average diameter of 0.5 micron and an average length of 300 microns and 0.6 g/l. of crocidolite fibers having an average diameter of 0.5 micron and an average length of 1500 microns, by agitation in a high shear mixer having a rotor diameter of 7 inches, at a speed of 1800 rpm.

An amyl acetate binder solution was prepared containing 4.75% by weight of neoprene, 0.2% by weight magnesium oxide and 0.24% by weight of zinc oxide, 0.05% by weight of tetraethylthiuram disulfide as a curing agent, 0.05% by weight sodium dibutyl dithiocarbamate as a curing agent, 0.11% by weight of phenyl-beta-naphthylamine as a stabilizer, and 94.7% by weight amyl acetate.

This was blended into the fibre slurry at the region of highest shear in a ratio of neoprene to fibres of 15:100 by weight. Neoprene was deposited on the fibres, so that the fibres were coated with about 15% by weight neoprene.

A thin cellulose paper having a thickness of 0.0045 inch and a weight of 2.65 g/ft<sup>2</sup> was placed on the foraminous belt of a Fourdrinier machine, and served as the foraminous base support for laydown of the microporous material. The paper was used as the base rather than the mesh, to ensure

a smooth-surfaced fine base layer. The paper was stripped from the microporous material after it had been laid down, and before curing.

The dispersion of fibres and binding agent was then flowed upon the paper support, and the resulting turbulence deflocculated some fibres, while some liquid drained out by gravity, thereby forming a thin first microporous layer of deflocculated fibres about 0.001 inch in thickness, of the mixed asbestos fibres, in which the fibres lay almost entirely in planes approximately parallel to the plane of the layer, and having an average pore diameter of 0.1 micron and a maximum pore diameter of 0.35 micron. The flow through the support slowed as the layer formed, and the fibres in the supernatant liquid reflocculated. The belt was passed under a doctor blade which broke up excessively large flocs in the supernatant dispersion. Thereafter, a vacuum of 15 inches of mercury was applied on the underside of the foraminous belt, causing the supernatant dispersion to flow through the thin layer, depositing the remaining mixed asbestos fibers on the thin layer, under pressure flow, and forming a coarse layer having an average pore diameter of 0.25 micron, a maximum pore diameter of 0.55 micron and a thickness of about 0.004 inch.

The bilayered sheet so formed had a thickness (uncompressed) of 0.006 inch, and was dried under infrared lamps, and then oven-cured for 20 minutes at 310°F. It had a water permeability of 10 gallons per minute per square foot at an applied pressure differential of 15 psi. The voids volume of the relatively coarse layer was found to be about 84%, and for the thin layer, it was 60%.

This material was then treated with a silicone resin, to render it water-repellent. The treatment was carried out by impregnation using a 5% (by volume) solution of the silicone resin solution in perchloroethylene, followed by evaporation of the solvent, and curing the resin at 40% relative humidity and at 25°C. for 18 hours. The deposition rate was approximately 0.1 cc. of solution per square centimeter of filter material, extending to the opposite side of the material. The dry permeability of the material at 28 cu. ft. per minute of air per square foot was unchanged by the treatment.

The liquid-wetted filter 76 was the same material, without the silicone resin treatment.

In use, medicament fluid containing both air and liquid enters via tubing 16 into the chamber 80 between the filter materials 64, 76. Fluid wets the liquid-wetted material 76, and as soon as the pores of this material are filled, air can no longer pass through.

On the other hand, liquid does not wet the liquid-repellent material 64, and air is consequently free to pass through this material, reaching the chamber 82 on the other side thereof, and being vented to the atmosphere through the port 32. Liquid passing through the liquid-wetted material 76 enters the chamber 84, whence it is delivered from the device through the outlet 36 to tubing 37.

The fluid inlet 31 and liquid outlet 36 are shaped to match selected one of any type of fluid line in the apparatus in which the air eliminator is to be used. The outlet 36 can also, for example, be adapted for connection directly to a Luer needle, instead of to a tubing leading to a Luer needle, as shown.

The air spring 34 is fed from chamber 80 via connector 33. As a volume of fluid pulses through tubing 16 and reaches the chamber 80, fluid pressure increases in the chamber. This pressure is most easily relieved by the flow of fluid through connector 33 which then acts as an outlet into air spring 34, and this then follows, compressing the air therein. Such flow continues until the pressure of the air in the spring balances the fluid pressure, and then ceases. When the syringe pump enters the suction stroke, fluid pressure begins to fall, whereupon the pressure of air in the spring 34 eventually exceeds the fluid pressure, and fluid is forced out from the spring, back into chamber 80, via connector 33. Now, fluid flow in line 16 has stopped, and reverse flow is prevented by duckbill valve 73. Thus, liquid passes through the filter 76 into chamber 84, and thence via outlet 36 to tubing 37. This tends to extend the period during which liquid flow proceeds in tubing 37 to the administration means. If the air spring 34 has a capacity to match the fluid volume delivered by the syringe in each pressure stroke in an appropriate proportional relationship that is readily ascertained in each apparatus, a continuous flow in tubing 37 can be assured by the air spring 34.

The air eliminator of *Figures 8 and 9* has a tubular housing 90 the open ends of which are closed off by flanged end caps 91, 92. The housing 90 is shown as closed, but it also can be perforated, to vent the air that is separated by the device to the atmosphere if desired. Each end cap has a recessed portion 93, at the center, engaging and centering within the housing a core tube 94 extending from end to end of the housing. This core limits the hold up volume in annular chamber 95, of which the core serves as the internal wall. At one end of chamber 95 is disposed outlet tube 96. The external wall of the chamber 95 is defined by a concentric stainless steel wire mesh tube 97, which also extends from end to end of the housing 90 and has its ends

seated in the recessed grooves 98, in the end caps 91, 92, thus locating it concentrically with respect to the core. The mesh serves as a support for a corrugated liquid-wetted tubular filter material 99. This material is of the membrane type, made of an acrylonitrile-vinyl chloride copolymer, cast on a nylon fabric support, and having a mean pore size of 0.45 micron and a thickness of 140 microns.

The filter 99 serves as the internal wall of an annular chamber 85, which is 1 to 25 mm. wide. At one end of chamber 85 is a fluid inlet tube 86. The outer wall of the chamber 85 is defined by a corrugated tubular liquid-repellent filter material which is supported on a perforated stainless steel tube 88. This material is also of the membrane type, with a polytetrafluoroethylene membrane, mean pore size 0.5 micron, on a polyvinyl chloride fabric, and a thickness of 125 microns. The filter tube 87 and perforated tube 88 extend from end to end of the housing, and their ends are located in recessed grooves 89, in the end caps 91, 92, which space them concentrically with respect to the other elements of the device. On the outer side of the tube 88 is an annular chamber 100, from one end of which leads the outlet tube 101.

The ends of the core 94, and tubes 97, 99, 87 and 88 are bonded to the inner face of the end caps 91, 92 by a layer of epoxy resin, forming a fluid-tight seal there.

In use, medicament fluid containing air and liquid enters the device via inlet tube 86, entering the chamber 85. The liquid quickly wets and saturates the liquid-wetted filter 99, and from that time blocks the passage of gas therethrough. The liquid passing through the filter 99 and mesh tube 97 enters chamber 95, and leaves the device via outlet tube 96, free from air.

The liquid-repellent filter material 87 blocks the entry of liquid, but is open to passage of air. Air passing through the filter 87 and tube 88 enters chamber 100, and leaves the device via outlet tube 101, free from liquid.

The air eliminator of *Figures 10, 11 and 12* has a shape curved to fit an arm or leg of the human body. The housing 110 is in two parts, 111, 112, with part 112 having a central recessed portion 113 in which a projecting portion 114 of part 111 nests. The two parts are solvent-fused together.

The recessed portion 113 of part 112 has a plurality of through holes 115 which serve as air vents, and in the recessed portion is disposed a liquid repellent filter material 116 of the type of *Figures 6 and 7*. This filter 116 is held at its periphery in the bite between housing parts 111, 112 and is solvent-bonded thereto in a leak-tight seal.

Housing part 111 has a bore 117 open

to the exterior at 118 and serving as a liquid outlet, and a bore 119 open to the exterior at 120 and serving as a fluid inlet. A plurality of cross grooves 121 are provided at the inner face 122 of part 111 and intersect bore 117 at crossing points 123 for liquid flow via the grooves to the outlet 118. To the face 122 of the part 111 across the grooves 121 is bonded a liquid wetted filter material 124 of the type of Figures 6 and 7. This is done before assembly of part 111 to part 112. In the assembly, filters 116, 124 are parallel, and can be from 0.5 to 5 mm. apart, defining a chamber 125 therebetween, into which opens bore 119.

In use, medicament fluid containing air and liquid enters the separator at inlet 120, and flows through bore 119 into chamber 125. Liquid passes through filter 124, grooves 121, crossing points 123 into bore 117, and leaves the air eliminator at outlet 118. Air cannot pass through the filter 124, but it does pass through filter 116, which in turn blocks the liquid. Air enters the holes 115, and is vented thereby to the atmosphere.

This device can easily be strapped or otherwise attached to the limb of a patient for use in administration of some liquid medicament.

The air eliminator of *Figures 13, 14 and 15* like that of *Figures 6 and 7* is in disk form of transparent polymethyl methacrylate resin. There are three housing portions 130, 131, 132, the central portion 131 being merely an annulus. The three portions are solvent-bonded together to form an integral fluid-tight housing. The inner face of portion 130 is provided with a plurality of shallow parallel grooves 133, running across of the surface of the disk, each interconnected at one end with an arcuate groove 134 running only from the first to the last groove 133 around the housing portion. The housing portion 132 is provided with a plurality of radial grooves 135 which intersect at the center 137 of the portion and concentric grooves 136 in a regular pattern. A plurality of segments 138 of the portion 132 are cut out, and serve as air vents over the grooves 136. Attached to the part 130 at the tops 140 of the raised portions between the grooves 133 is a liquid-wetted filter material 143. This material is the same as that of *Figures 6 and 7*. The housing portion 130 has a liquid outlet 139. The groove 134 connects the end of each of the grooves 133 with the outlet 139. Thus, a fluid path is formed from the filter 143 via the grooves 133 into groove 134 leading to the fluid outlet 139. Attached to the inner face of housing portion 132, at the solid portion 149 between the grooves 135, 136, is a liquid-repellent filter material

150. This material is the same as that of *Figures 6 and 7*.

The housing portion 130 is provided with two connectors 141, 142, for attachment to a tubing, such as 16, and an air spring, such as 34. When annulus 131 is bonded in place to each of the housing portions 130, 132, the liquid-repellent filter material 150 is thereby held in a position spaced from and parallel to the liquid-wetted filter material 143, attached to the raised portions between crosswise grooves 135 of the housing portion 130, defining therebetween the chamber 148. The spacing between the filters 143, 150 can be for instance 0.5 to 2 mm. The chamber 148 thus defined has opposed parallel walls, made up of the liquid-repellent and liquid-wetted materials 143, 150. The connectors 141, 142 communicate with the chamber 148 between the two filter materials 143, 150.

In use, medicament fluid containing liquid and air enters the device via the fluid inlet 141, thus entering the chamber 148 between the liquid-repellent and liquid-wetted filter materials. The liquid quickly wets the liquid-wetted material 143, and after the pores therein are all filled, this material becomes impenetrable to air, while liquid passes freely therethrough, into the grooves 133, and then into the intersecting groove 134, running therethrough to the liquid outlet 139, whence liquid is delivered from the device, quite free from air. Air which cannot pass through the liquid-wetted material 143 reaches the liquid-repellent material 150, passes through it into the grooves 135, 136 of the housing portion 132, and is vented thence via the segmental openings 138 to the atmosphere.

The air cushion 34 attached to connector 142 functions in exactly the same manner as described in connection with *Figures 6 and 7*.

The air eliminators shown in the drawings as described above are useful to separate air from liquids in any type of medicinal and chemical application. They can, for instance, be used both to clear the medicament administration apparatus line of air and to prevent the introduction of air into a patient receiving an injection of any type of fluid medicament, such as a parenteral fluid, blood plasma, intravenous feeding solutions, or needle-blockage-preventing flows. Such fluids can be delivered to a patient under high pressures, such as are encountered when the fluid delivery is effected by means of a syringe pump, and will prevent the introduction of air into the patient, at all pressures below the bubble point of the liquid-wetted filter material that is used, both at the beginning of the introduction of the liquid.

The air eliminators are quite versatile, and the construction design is such that they can

be adapted to meet many air-liquid separation requirements. The essential materials of which it is constructed are known, and available, and readily lend themselves to the construction of devices of any desired size. For medical applications, it is usually preferable that the separator chamber between the two filter materials have as small a fluid volume as possible, less than 1 cc., and preferably less than 0.5 cc. The relative proportion of available surface area for the liquid-wetted and liquid-repellent materials can be adjusted as required, and will depend upon the relative volumes of fluid being processed, and of liquids and air being passed therethrough.

Because of the desirability of preventing distortion, and for greater strength and resistance to rupture, in most applications the housing is preferably of a rigid construction, using rigid sheets or molded or cast plastics material parts, or metal, thus making it possible for the device to resist internal fluid pressures up to the bubble point of the filters used. If high fluid pressures are not to be encountered, however, the housing can be of a flexible construction, in which case it can be made of flexible sheet material, such as polyvinyl chloride, vinyl chloride-vinylidene chloride copolymers, polyesters, polyethylene or polypropylene sheet.

It is frequently helpful that the housing be transparent, so that the functioning of the device and the condition of the liquid-repellent and liquid-wetted filter materials can be observed. Inasmuch as these materials also serve as filters, and will remove suspended solid material, such as dirt and other contaminants, which can lead to blockage.

Thus, for example, the housing can be constructed of rigid plastics material that is also transparent, such as polyethylene, polymethyl methacrylate, polycarbonates, polymethyl acrylate, polymethyl pentene-1, polyvinyl chloride, and vinyl chloride-vinylidene chloride copolymers. Translucent materials, such as polypropylene, polyethylene, urea-formaldehyde, and melamine-formaldehyde polymers, can also be employed. Other plastics materials that are particularly suitable are polystyrene, polyamides, polytetrafluoroethylene, polyfluorotrichloroethylene, polyesters, phenol-formaldehyde resins, polyvinyl butyral, cellulose acetate, cellulose acetate propionate, ethyl cellulose and polyoxymethylene resins.

Metal housings can be used. Suitable metals include stainless steel, aluminum, and stainless alloys, such as nickel, chromium, vanadium, molybdenum, and manganese alloys. The housing material should, of course, be inert to the fluids being processed.

The filter materials, of which one is

liquid-repellent and one is wetted preferentially by the liquid, can have any desired pore size according to the minimum bubble point required, according to the nature of the fluid being treated, and the nature of the contaminants, if any, to be removed. Since most filter materials are wetted by some liquids, and repel others, the materials chosen for each filter will depend upon the fluid being processed. If water is the liquid, then one of the filter materials is hydrophilic, and the other is hydrophobic.

In most cases, in order to be effective in repelling and therefore not passing air, the liquid-wetted filter material should have a pore size of less than about 3 microns, and preferably less than 1 micron. In order to be effective in repelling and therefore not passing a liquid, the liquid-repellent filter material likewise should have a pore size of less than about 3 microns, and preferably less than about 1 micron. For bacteria removal purposes, as previously indicated, the pore size should be less than about 0.3 micron, and preferably less than 0.2 micron. A filter material that has too large a pore size can have the pore size reduced by impregnation, or coating, or both, with particulate and/or fibrous material. Such materials and procedures are known.

Thus, there can be used as the filter material woven or nonwoven textile materials made of cotton, jute, sisal, hemp, flax, linen, wood fibre, metal wire, such as stainless steel, copper and aluminum, plastics material filaments (monofilaments and yarn) such as nylon, polyvinyl chloride, polyacrylonitrile, esters of terephthalic acid and ethylene glycol, cuprammonium rayon, acetate rayon, viscose rayon and polyvinylidene chloride; sintered composites made from metal powder or particles, such as stainless steel, copper, bronze, or monel, or from plastics material particles, such as polyvinyl chloride, nylon, polyethylene, polypropylene, polytetrafluoroethylene, and polyfluorotrichloroethylene; glass and ceramic materials; papers of various types, made up of cellulose fibres, cellulose cloth, plastics material fibres, such as polyvinyl chloride, cellulose acetate, polyvinylidene chloride, nylon, and any of the other plastics material filaments mentioned above, taken singly or in any combination; and microporous sheets, such as synthetic resin and cellulose derivative membrane filters.

Impregnated and/or coated microporous filter sheet materials meeting these general requirements and that in particular can be made with less than 0.3 micron pores and thus are useful for the removal of harmful micro-organisms include the microporous materials of U.S.A. Patents Nos. 3,158,532, 3,238,056, 3,246,767 and 3,353,682. Also useful for this purpose are microporous cera-

mic filters and the microporous membrane filters described in U.S. Patents Nos. 1,421,341, 1,693,890, 1,720,670, 2,783,894, 2,864,777 and 2,944,017.

5 Liquid repellency is obtained, if the filter is of a material that is wetted by the liquid, by treatment with a material that repels the liquid when disposed on the surfaces of the pore walls of the filter material. The repellent material can be applied from a solution or dispersion thereof, in a solvent or dispersant which desirably includes a binder, to retain the repellent on the pore wall surfaces, unless the repellent is reactive therewith, and can bond itself thereto.

10 The application can be by printing, spraying, coating, impregnating, dipping, or by exposure to a vapor, such as that of a low boiling point silicone compound. It is necessary to use a technique that results in thorough treatment of the entire length of the pores, from surface to surface of the filter material. This requires impregnation of the wall surfaces of the pores from end to end, best achieved by allowing the solution or dispersion of the repellent to flow into and through the pores in the treated zone, by capillarity or pressure application.

15 It will be appreciated that in nonwoven substrates, such as paper, nonwoven bats, and microporous layers formed by laydown from a fluid dispersion, the through pores that extend from one surface to another are composed of interconnected pores which are the interstices between the particulate material of which the material is made.

20 The amount of repellent that is required depends upon the effectiveness of the material as a repellent, and the volume of pores being treated. Usually less than 25% by weight of the volume being treated and preferably from 0.025% to 15% by weight of the volume is sufficient.

25 The repellent is chosen according to the liquid suspending medium being filtered. It must repel such liquid, or be rendered so *in situ* on the pore surface.

30 For a hydrophobic or water-repellent surface, there can be used silicone resins and silicone oils of the general type  $R_n-Si-O-Si-R_n$ , where  $n$  is 1 or 2.  $n$  is 1 in the case of the oils, and  $n$  is 2 in the case of the resins, which contain crosslinks between chains. Mixtures containing species in which  $n$  is from 1 to 3 can also be used.  $R$  is a hydrocarbon group having from one to eighteen carbon atoms.

35 Also useful are the quaternary ammonium salt derivatives of silicone compounds described in U.S. Patent No. 2,738,290. These are substantive to cellulosic filter materials, as noted in the Patent. Also, the hydrophobic oils and waxes can be used, in appropriate circumstances, where they can be made permanent.

If the filter material is liquid-repellent, and it is desired to make it liquid-wetting, it is advantageous to apply a liquid-wetted material thereto. The same treatment principles and proportions apply to liquid-wetted materials as to liquid-repellent materials, but the proportions are less, of the order of 0.1% by weight of the wetting agent, or less. Typical wetting agents that are suitable are polyvinyl alcohol, alkyl aryl polyether alcohols, melamine-formaldehyde resins, and sodium lauryl sulfate. These wetting agents can be applied from a solution.

Some liquid-repellent materials can also be made liquid-wetted temporarily by adding a solution of the liquid containing 0.5% by weight or less of a wetting agent. The wetting agent will make it possible for the liquid to wet, impregnate and saturate the material quickly with the liquid, which will then stay there until the material is dried out, and throughout the intervening period, the material will behave as though it were really liquid-wetted.

40 The filter material that is liquid-repellent and therefore passes the air being separated from the liquid is so placed in the housing that the air can reach it and pass through it to the air outlet in the housing. Inasmuch as air under normal conditions rises, this means that at least a part of the liquid-repellent filter preferably is at an upper portion or wall of the chamber in the housing. If the liquid-repellent filter is confined to a lower portion of the housing, the air may not pass through it until an air pocket deep enough to reach the uppermost portion of the liquid-repellent filter has built up in the chamber. The building up of such an air pocket is not a disadvantage, if the liquid-wetted filter material is still fully open to the passage of liquid, and is not covered by or immersed in the air pocket, but such a device may be position-sensitive. It is therefore less preferred, for some uses.

45 For convenience of construction and minimum volume, in an air eliminator as herein described the liquid-repellent and liquid-wetted filter materials are substantially parallel, are as close together as is practical and still define a space therebetween that is open to the air-liquid mixture to be separated, and define opposed parallel walls of the housing chamber. A suitable spacing of the filters is from 0.25 mm. to about 5 mm., for medicinal uses, as an air separator in a supply line to a patient. For other purposes, there is no limit except that dictated by the dimensions and flow requirements of the system in which it is to be placed.

50 In the simplest construction, the separator walls are planar, as well as parallel. However, in this case the liquid-repellent wall normally must be uppermost, if air blockage is to be avoided.

Another type of construction, which avoids the possibility of air blockage in the chamber, regardless of the position of the device, has the liquid-repellent and liquid-wetted separator walls arranged in parallel in a U configuration, with the air being vented either on the exterior or the interior walls of the U. In either case, regardless of the position of the device, a portion of the liquid-repellent wall is always uppermost in the device, so that air can reach it and thus be vented, even if other portions of the same liquid-repellent wall are immersed in liquid.

It is also possible to arrange the liquid-repellent and liquid-wetted walls in an N, a V or even a W configuration, with similar results. One of the filter materials can cross the chamber diagonally or at an angle to the other filter material and can if desired contact the latter at one end in an S or Z configuration.

The liquid-repellent and/or liquid-wetted materials can also be arranged in a corrugated or undulating configuration, or in a raised, waffled or dimpled pattern for a greater surface area in a small space. In this case, the surface of the filters is uneven, so that air blockage due to air pockets is unlikely, since the air will not be in contact with all portions of the filter. If the peak portions of either the liquid-repellent or the liquid-wetted filter material are virtually in contact with the other, the vale portions then provide space for passage of liquid therebetween, while the close spacing of the abutting peak portions ensures that air can reach and escape through the liquid-repellent filter, whatever the position of the device. Thus, this also avoids position-sensitivity, as do the N, S, U, V, W and Z configurations.

For simplicity of construction, the housing is best formed in two or three mating pieces, which when assembled define the separator chamber therebetween, with the liquid-repellent filter material fixed in one portion of the housing, and the liquid-wetted filter material fixed in another portion of the housing, at opposite sides of the chamber, and preferably parallel or nearly parallel to each other in the final assembly. These parts can be separately moulded, and then attached together, by bolts, or by heat-fusing, or by solvent- or adhesive-bonding. In the case of plastics materials, solvent-bonding is a preferred attachment technique, because it eliminates the presence of extraneous adhesives, does not affect transparency at the joints of a transparent housing, and is also leakproof.

The housing parts are constructed so that the filter materials contained therein are spaced from the outer walls thereof, and define spaces therebetween. The housing part containing the liquid-repellent material

has an air outlet or vent communicating with the space on the outside of the liquid-repellent material, and the housing part containing the liquid-wetted material has a liquid outlet or vent communicating with the space on the outside of the liquid-wetted material. The housing thus has at least three chambers, the intermediate chamber being that to which the fluid containing both air and liquid is delivered for separation of the air therefrom, and two outer chambers on opposite sides of the liquid-repellent and liquid-wetted materials, respectively, being adapted to vent air separated from the liquid, and to deliver liquid from which air has been separated respectively.

The limiting fluid pressure at which a liquid repellent filter material will no longer resist passage of liquid therethrough is readily determined, just as is the limiting pressure beyond which a filter wetted by a liquid will pass a gas. Both limits are significant in the air eliminators herein described, the first because it is the limiting pressure at which the air eliminator begins to leak fluid through the air vent, and the second because it is the pressure at which the system will begin to leak air into a patient. Neither limit can be exceeded, therefore.

It is relatively easy to select a liquid-wetted filter material having a high enough bubble point to resist passage of air at all fluid pressures that might conceivably be encountered. However, it is more difficult to select a liquid-repellent material that will resist passage of liquid at fluid pressures at which the liquid-wetted filter material easily resists passage of air. The air spring or cushion provides a way around this difficulty, in that it reduces the peak pressure in the apparatus, that is reached in the course of the pumping stroke of the syringe plunger.

The air spring or cushion is a dead-end air chamber on the upstream side of the air eliminator. When a pressure surge reaches the spring, the surge is at least partially absorbed by flow of fluid into the air spring, compressing the air normally contained therein, and correspondingly reducing fluid pressure on the upstream side of the liquid-wetted and liquid-repellent filters. This pressure reduction greatly improves the likelihood of preventing leakage of either air or liquid past the wrong filter at this pressure surge. Then, on the suction stroke of the syringe plunger, the pressure is reduced, and the compressed air in the spring forces the fluid out again. This not only tends to equalize fluid pressure differences between the pressure and suction strokes of the plunger, but also promotes a more uniform flow of liquid to the patient.

It is possible to design the air spring so

that a steady flow of liquid is supplied at the delivery means of the apparatus. This flow will necessarily be at a slower rate than the rate of flow delivered by the syringe on the pressure stroke, but it will be continuous, and at a relatively uniform pressure. All that needs be done is to adjust the capacity of the air cushion or spring to equal the volume of fluid delivered per stroke, and appropriately adjust the flow delivery capacity of the delivery means so as to deliver this volume of fluid (minus the volume of air) only in the time required for the syringe pump to complete a cycle of one pressure and one suction-stroke.

The air cushion is normally dimensioned so as to reduce the peak fluid pressure at the air eliminator to no more than 25% above the normal peak pressure on the pressure stroke. This is a significant reduction, since the peak pressure can be as much as six times higher, or more. If the volume of the air spring is equal to the volume of fluid delivered per stroke of the syringe, the peak pressure is reduced by 50%. Each doubling of the volume gives a further reduction of 50%. Since pressure is reduced, flow rate is also correspondingly reduced.

The air spring or cushion can take the form of a fluid-tight chamber or pocket of any suitable dimensions, according to the volumes of fluid delivered per stroke of the syringe plunger, and the frequency of the strokes. The damping action can be complemented by appropriate dimensioning of the inlet and outlet access openings or passages leading to the chamber.

The chamber walls can be resilient, aiding the damping action. The use of resilient flexible tubing is particularly advantageous.

The air spring pressure chamber walls can be transparent or translucent, so the point of advance of the fluid therein can be observed by locating the meniscus. Since the fluid pressure is a function of the advance of fluid into the chamber, against the air pressure therein, the walls can be marked in a scale, from which pressure can be read off directly, after calibration against a pressure gauge. In this event, the spring chamber is preferably in the form of a narrow tube, with walls which are rigid or distensible by only an insignificant amount.

The administration apparatus of the invention is suitable for administration of liquid medicaments of all types, including plasma nutrient solutions, vitamins, and drugs, such as antibiotics, narcotics, parenteral fluid, for intravenous, subcutaneous or intraperitoneal injection, or for oral, vaginal or rectal administration. It is easily and quickly attached to standard administrative supply containers, and administration kits, such as needles, nipples, and spouts. It is sterilizable as a unit, before

use, and is thrown away as a unit, after use. The parts although new are inexpensive, and due to savings in labour and the ease and safety of handling, it is less expensive to use than most apparatus now in use, made up of various combinations of disposable parts and of parts that must be re-used, after re-sterilization.

Having regard to the provisions of Section 9 of the Patents Act, attention is directed to the claims of Patent Nos. 1,232,655 and 1,262,146.

#### WHAT WE CLAIM IS:—

1. A sterile disposable apparatus for administering gas-free liquid to a patient, comprising a connector having three branch passages one of which has a non-return valve adapted to allow the admission to the connector of a gas-containing liquid, and another of which has a non-return valve adapted to allow the exit of the gas-containing liquid from the connector and is connected by tubing to an air eliminator in an air- and liquid tight manner, the air eliminator being adapted to remove gas from the gas-containing liquid; and delivery means connected by tubing with the air eliminator in an air and gas tight manner for delivery to a patient of gas-free liquid received from the eliminator.

2. An apparatus according to claim 1, further comprising a syringe attached to the third branch passage of the connector.

3. An apparatus according to claim 1 or 2, comprising an air cushion device communicating with the upstream side of the air eliminator.

4. An apparatus according to claim 2, comprising an air cushion device communicating with the upstream side of the air eliminator, which air cushion device comprises a chamber, and an inlet communicating the chamber with the upstream side of the air eliminator, the inlet and the chamber being dimensioned to absorb at least in part pressure surges created by a pumping action of the syringe.

5. An apparatus according to claim 4 wherein the chamber walls are of transparent or translucent material.

6. An apparatus according to claim 5, wherein the chamber walls are provided with a visual scale correlating fluid advance in the chamber with fluid pressure therein.

7. An apparatus according to any preceding claim, comprising a visual flow indicator on the upstream side of the connector.

8. An apparatus according to any preceding claim wherein the connector is made of a plastics material and holds the valves therein as one unit.

9. An apparatus according to claim 8, wherein the connector has in at least one of the two valve-containing passages a fitting

retaining the valve in the passage and having a passage therethrough.

10. An apparatus according to claim 9, wherein the or each fitting is secured to the connector housing and the connector housing is in one piece.

11. An apparatus according to any one of claims 1 to 8, in which each of the valves is a duckbill valve.

12. An apparatus according to any preceding claim, in which the passage in the connector for admission of gas-containing liquid is at right angles to the passage for exit of gas-containing liquid, and the third passage is in alignment with the passage for exit of gas-containing liquid.

13. An apparatus according to any preceding claim, in which the interior volume of the connector between the valves is less than 1cc.

14. An apparatus according to any preceding claim in which the connector housing is formed of moulded plastics material.

15. An apparatus according to claim 14 wherein said connector housing is rigid.

16. An apparatus according to any preceding claim, wherein one of the non-return valves is associated with a resilient spring of foamed material to ensure a leak-tight seal when the valve is closed.

17. An apparatus according to any preceding claim, wherein the air eliminator comprises a housing, a chamber in the housing, of which chamber one wall comprises a filter material that is wetted by a liquid to be passed through the air eliminator housing, and another wall comprises a liquid-repellent filter material that is not wetted by the liquid passing through the housing; an inlet in the air eliminator housing for delivering fluid comprising gas and liquid to the chamber between the liquid-wetted and liquid-repellent filter materials; a liquid outlet in the air eliminator housing on the opposite side of the liquid-wetted material to the inlet; and a gas outlet in the air eliminator housing on the opposite side of the liquid-repellent material to the inlet.

18. An apparatus according to claim 17, wherein the liquid-wetted and the liquid repellent materials of the air eliminator have an average pore size less than about 0.3 micron.

19. An apparatus according to claim 17 or 18 wherein the air eliminator is of plastics material.

20. An apparatus according to any one of claims 17 to 19 in which the liquid-wetted and liquid-repellent filter materials of the air eliminator are at opposite sides of the chamber therein.

21. An apparatus according to any one of claims 17 to 20, wherein the liquid-wetted and liquid-repellent walls are spaced from each other by a distance of less than 5 mm.

22. An apparatus according to any one of claims 17 to 21 wherein the filter materials are each microporous.

23. An apparatus according to any one of claims 17 to 22 in which the air eliminator housing is in three parts, comprising an annulus defining a wall of the chamber between the liquid wetted and liquid repellent filter materials and having the fluid inlet formed therein, the annulus being intermediate and attached in a fluid tight seal to two outer portions in one of which is disposed the gas outlet, the liquid repellent filter material being disposed across the line of flow between the chamber and the gas outlet, and in the other of which is disposed the liquid outlet, the liquid-wetted material being disposed across the line of flow between the chamber and the liquid outlet, so that all fluid entering the chamber must pass through one of the filter materials to reach an outlet.

24. An apparatus according to any one of claims 17 to 22, in which the air eliminator housing is in two parts, in one of which is disposed the liquid-repellent filter material across the line of flow between the chamber and the gas outlet, and in the other of which is disposed the liquid-wetted filter, across the line of flow between the chamber and the liquid outlet, so that all fluid entering the chamber must pass through one of the filter materials to reach an outlet.

25. An apparatus according to claim 17, wherein the air eliminator housing has facing the liquid-wetted filter material, a surface in which a plurality of channels are formed to permit fluid flow from the liquid-wetted filter material towards the liquid outlet.

26. An apparatus according to claim 25, wherein the channels are in the form of a plurality of parallel grooves connected together by an intercommunicating groove.

27. An apparatus according to claim 2, wherein the syringe has a plunger capable of being reciprocated by a pump drive.

28. A disposable fluid administration apparatus substantially as described with reference to the accompanying drawings.

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Printed for Her Majesty's Stationery Office by Burgess & Son (Abingdon), Ltd.—1972.  
Published at The Patent Office, 25 Southampton Buildings, London, WC2A 1AY,  
from which copies may be obtained.

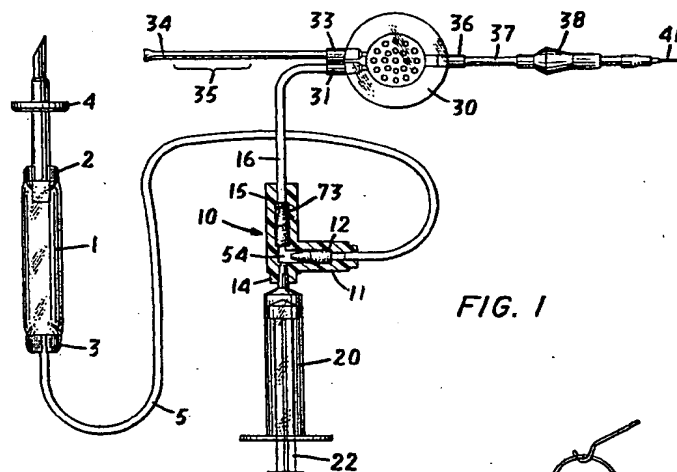


FIG. 1

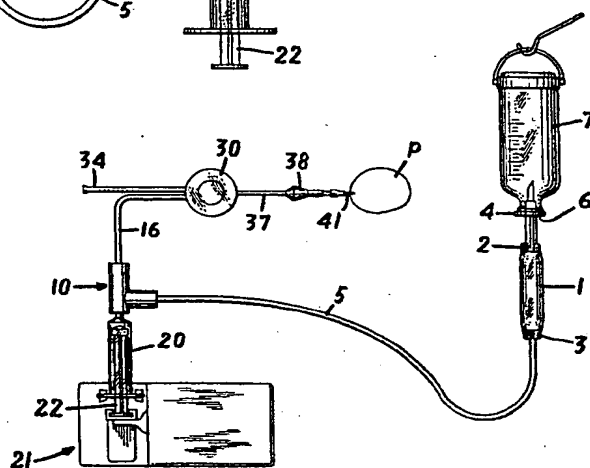
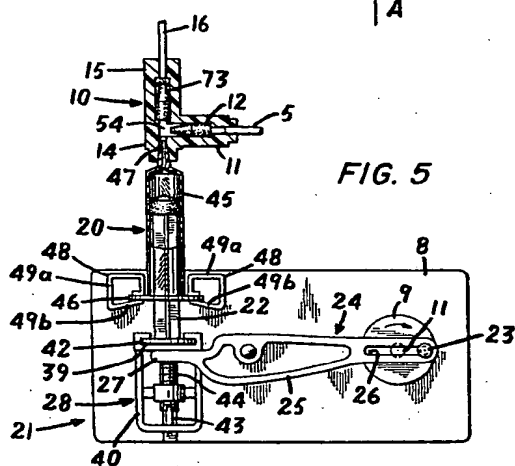
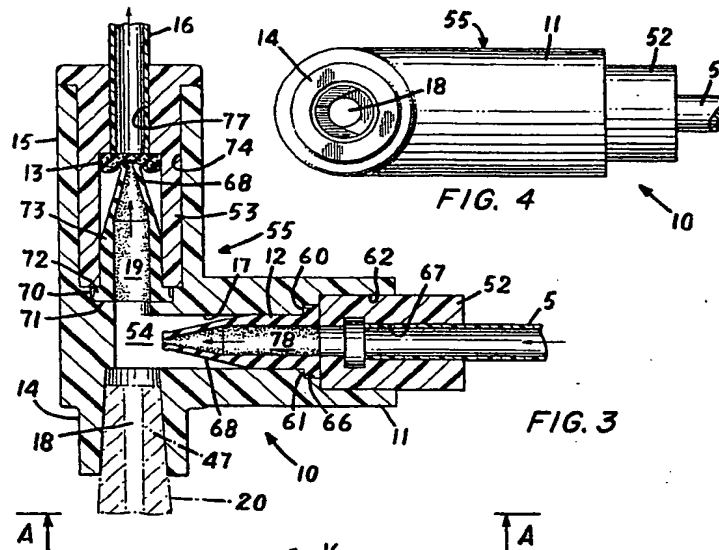


FIG. 2



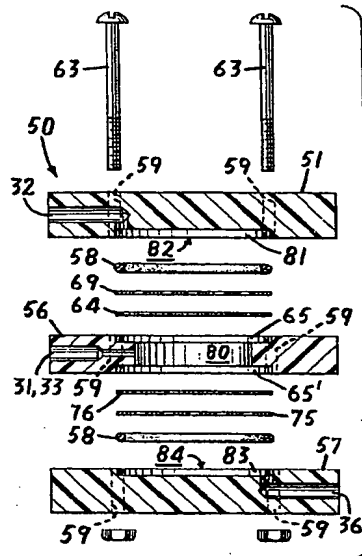


FIG. 6

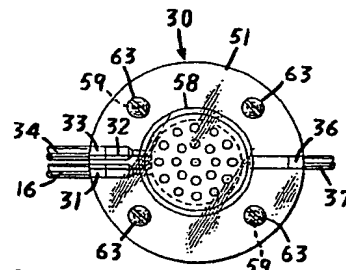


FIG. 7

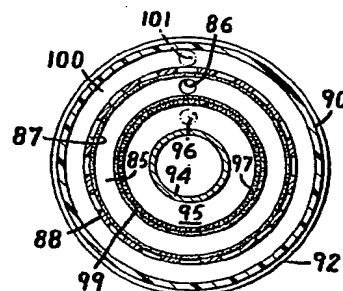


FIG. 8

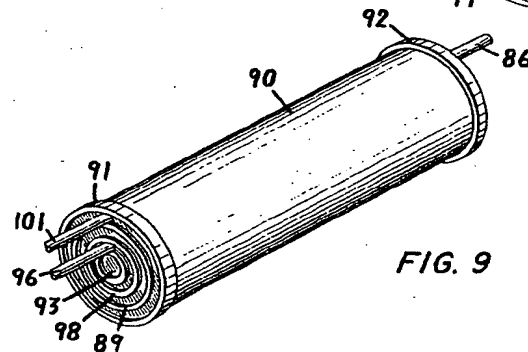


FIG. 9

